

REMARKS

Claims 1, 2, 7, 12 and 18 are rejected under §102(b) as being anticipated by Koyata.
Claims 1-3, 6, 8, 11, 12, 24 and 37 are rejected under §102(b) as being anticipated by Hake.
Claims 1-3, 8, 9, 11, 12, 37, 39, and 40 are rejected under §102(b) as being anticipated by Salerno.

Claims 4, 10, 13-17 and 25-29 are rejected under §103(a) as being unpatentable over Koyata. Claims 4, 13-17, 19-23, 25-36 and 38 are rejected under §103(a) as being unpatentable over Hake. Claims 41-42 are rejected under §103(a) as being unpatentable over Salerno.

Claims 1, 2, 12, 37, and 41 have been amended. Claims 1-42 remain in this application. None of the amendments introduces new matter and are made in a bona fide effort to place the claims in better form for allowance or in the alternative in better form for the purpose of consideration on appeal.

For the reasons discussed below, all of the rejections are traversed and it is Applicants' belief that the claims, as amended, are in condition for allowance.

1. Anticipation Rejection - Claims 1-3, 5-9, 11, 12, 24, 37, 39 and 40

Claims 1-3, 5-9, 11, 12, 24, 37, 39 and 40 are rejected as anticipated based on either the Koyata reference, the Hake reference, or the Salerno reference. None of the cited references discloses each and every element of the present claims, as amended. Each of these references is discussed in turn.

A. The Koyata Reference:

Applicants respectfully state that the Koyata reference does not disclose each and every element of claims 1, 2, 7, 12, and 18. The claims as amended require that the distal portion be substantially rigid and that it include a distal end which is offset from the main portion. The

Koyata reference does not disclose such a configuration.

The Koyata reference discloses a distal end 5 connected to a bendable tube 4, which in turn is connected to a main portion 3. The invention of claims 1, 2, 7, 12, and 18 as amended, however, specifies that the distal portion be substantially rigid and include a distal end that is offset from the main portion. In other words, the offset of the claimed invention is fixed.

The Koyata reference, by contrast, discloses a distal portion that includes the rigid distal end 5, and a bendable tube 4. The bendable tube 4 enables the distal end 5 to be moved laterally by retracting a string connected to the distal end. Such a combination does not disclose a distal portion that is substantially rigid because bendable tube 4 is not substantially rigid. The bendable tube 4 of Koyata does not prevent further deflection of the bendable tube 4 and the distal end 5 combination as does the substantially rigid distal portion of the claimed invention. As such, the claimed distal portion is not disclosed by the Koyata reference, and therefore, the Koyata reference does not anticipate claims 1, 2, 7, 12 or 18 of the present application.

Indeed the bendable tube 4 and rigid distal end 5 combination taught by Koyata would not be suitable for the purpose of the present invention. As discussed at pages 11-12 of the present application, the substantially rigid distal portion and flexible main portion provide advantages over the prior art.

The distal portion 16 is advantageously pre-bent or pre-curved through an acute angle α in the range of 3 to 30 degrees, most preferably about 20 degrees, and is sufficiently stiff or flexurally rigid to substantially maintain the preselected acute angle. This provides the advantage of an endoscope in which the angle of view is preferably at an acute angle relative to the principal longitudinal axis of the endoscope, thereby affording a wider field of view as the endoscope is rotated through 360 degrees about its longitudinal axis. The pre-curved distal portion 16 also allows the light guide 14 to more easily follow the curvature of the endotracheal breathing tube. This can be accomplished by rotating the endoscope so that the distal portion 16 is curved in the direction of curvature of the breathing

tube prior to advancing the lightguide 14 through the breathing tube. Yet another advantage of the pre-curved or bent distal portion 16 is that the terminus of the light guide 14 can be kept from scraping along the inner wall of the breathing tube by steering the endoscope as described above for traversing bends in the breathing tube. The pre-curved distal portion 16 provides for the distal tip 32 to be laterally offset from main portion 31. This offset can be used to advantage to alleviate the problem of the distal end scraping up deposits on the inner wall of the breathing tube by keeping the distal tip 32 substantially displaced from the inner wall as the light guide 14 is advanced through the breathing tube. Without the offset, such deposits might collect on the objective end of light guide 14 and obscure or distort the view through the imaging fiber optic bundle.

By contrast, the apparatus disclosed in Koyata does not include a distal portion that will maintain its offset as it is inserted through an intubation tube. Instead, the distal end 5 and flexible tube 4 combination of Koyata will undesirably flex if the distal end 5 encounters deposits within the endotracheal tube since the deflection of the distal end 5 and flexible tube 4 combination is only constrained in one direction, i.e., the sting only prevents the tube from straightening. There is nothing to prevent the flexible tube 4 from deflecting further and even possibly bending upon itself. Therefore, the Koyata reference fails to disclose this claim element.

Applicants also respectfully disagree with the conclusion in the Office Action that the distal end 5 is connected to the main portion 3. The cited portion of the Koyata reference clearly states that the distal end 5 is connected to tube 4, which in turn, is connected to the main portion 3. In other words, the main portion is connected to the tube 4, not the distal end 5. Therefore, as discussed, to the extent the Koyata reference can be interpreted as disclosing a distal portion, it must include distal end 5 and tube 4, which is not substantially rigid as specified in claims 1, 2, 7, 12, and 18 as amended.

As discussed in the specification, a reason for the offset distal end is to prevent materials from being lodged in the distal end of the endoscope that would otherwise obscure the viewing

field as it is guided down an endotracheal tube that may have biological materials collected therein. There is no disclosure to any similar purpose for the Koyata device.

For at least the reasons stated, Applicants respectfully state that the Koyata patent does not anticipate any of claims 1, 2, 7, 12, and 18 as amended.

B. The Hake Reference:

Applicants respectfully state that the Hake reference does not anticipate any of claims 1-3, 6, 8, 11, 12, 24 and 37 because it does not disclose each and every element of the claims.

The claims specify that the distal portion is substantially rigid. The Hake reference does not disclose this configuration. Instead, the Hake reference specifically states that each of its segments, e.g., 14A and 14B, and the overall tube 10 is flexible. Also, claims 1 and 37, as amended, state that the distal portion is fixedly substantially rigid, unlike the adjustable segments of Hake.

Also, with respect to claim 2, the Hake reference cannot include a distal portion that has a substantially rigid outer surface. In order for the individual segments, e.g., 14A and 14B, to be adjustably bent through use of internal air bladders, they cannot have a rigid outer surface. Indeed, they are described as elastic. (Col. 5, ll. 46-48). Therefore, claim 2 is not anticipated.

With regard to claim 3, there is no disclosure in the Hake reference to a pre-curved rest orientation. As such, claim 3 is not anticipated for this further reason.

With regard to claim 6, it is specified that the distal portion includes a proximal end and a distal end, wherein the proximal end is axially aligned with the main portion, and the distal end diverges at an acute angle from the proximal end. There is no disclosure in the Hake reference of a distal portion, wherein a proximal end has an *axis* that diverges distally from an *axis* of a distal

end. The requirement of divergent axes denotes intersecting linear or substantially linear sections. The Hake reference, at best, discloses curved segments. As such, there is no axis for either a distal end or a proximal end of a distal portion. Thus, claim 6 is not anticipated for this additional reason.

Similarly, claim 12 also requires divergence of the distal portion relative to the main portion at an acute angle. Each of the segments 14 that make up tube 10 in the Hake reference are adjusted only in curved relation with one another. As such, there is no acute angle formed between any distal portion or main portion. Claim 12 is not anticipated for this additional reason.

Claim 24 similarly includes a requirement whereby a first end of the distal portion is angularly disposed from the second end of the distal portion. Each of the segments 14 that make up tube 10 in the Hake reference are adjusted only in curved relation with one another. As such, there is no angle formed between any first or second end of the distal portion. Claim 24 is not anticipated for this additional reason.

Also, with respect to all of the claims rejected as anticipated by Hake, Applicants again respectfully submit that the Hake reference does not disclose a main portion and a distal portion as claimed. Applicants submit that segment 14A is identical to segments 14B and 14C and therefore, in actuality, is at best part of the main portion of the endoscope. Indeed, the Hake reference states that “[t]he flexible tube 10 is comprised of a series of connected segments 14. Each segment 14 ... constitutes a continuous portion of the tube 10” (col. 4, ll .15-19). The Office Action has, in effect, taken the main portion of the endoscope and arbitrarily decided that it ends at a certain point and the remainder is a separate component. There is no grounds for doing so in that the Hake reference does not disclose that parts 14A can be considered a separate component.

Component 14A also does not form a distal portion having a distal end as claimed. As stated in Hake, "the construction and operation of the individual segments 14 is described by reference to the end segment 14A *near the distal end 12* of the endoscope." (col. 4, ll. 31-34). As such, the component 14A, which is suggested by the Office Action as the distal portion does not include a distal end.

The device disclosed in the Hake reference is also extremely complex compared to the claimed invention. The device disclosed in the Hake reference includes multiple moving parts controlled by inflatable and extendible conduits.

As such, none of claims 1-3, 6, 8, 11, 12, 24 and 37 are anticipated. Applicants respectfully request that the rejections on this basis be withdrawn.

C. The Salerno Reference:

Applicants respectfully state that the Salerno reference also does not anticipate any of claims 1-3, 5, 8, 9, 11, 12, 37, 39, and 40 because it does not disclose each and every claim element.

As stated in Applicant's first response, each of the claims of the present application specifies a flexible main portion. The term flexible is explained in the specification as a structure that is capable of bending without excessive resistance.

An endoscope having an elastically flexible light guide that can bend to relatively small radii without excessive resistance to flexure is more suitable for inspecting previously placed breathing tubes. (p. 3, ll. 31-35).¹

As an elastically flexible light guide is inserted into a previously placed breathing tube, the distal end of the light guide can follow the inner wall of the curved

¹ As a result of a clerical error, page 9 of the specification was referred to in Applicant's first response. The correct page is page 3.

breathing tube along the outer radius of the bend. Lateral forces imposed on the distal end of the light guide by the wall of the breathing tube cause the flexible light guide to bend, generally following the curvature of the breathing tube. Consequently, the light guide can traverse the full length of the breathing tube while being pushed from an external location. (p. 4, ll. 1-11).

By contrast, malleable guides are those that can be bent or curved from its ordinarily straight configuration and hold the desired configuration without springing back to the original straight configuration.

When inspecting a previously placed breathing tube, use of an endoscope having a plastically and inelastically malleable light guide has some disadvantages. The light guides of such endoscopes are usually too stiff to easily traverse the bend of the breathing tube while being pushed from the outside. Such bends are often curved to relatively small radii of curvature. (p. 3, ll. 5-11).

The claims specifically describe the main portion as "flexible." As such, Applicants respectfully disagree with the statement in the Office Action that the claims do not recite the feature on which they rely to distinguish over the Salerno reference. The term flexible, as explained in the specification is different from malleable. Therefore, the probe disclosed in the Salerno reference to a malleable guide – "[t]he instrument has a malleable stylet (or probe) ..." (col. 1, ll. 66-67) – does not anticipate any of claims 1-3, 5, 8, 9, 11, 12, 37, 39, and 40.

As discussed in the specification of the present application, the Salerno probe would not be suitable for the present invention. The Salerno device is bent to accommodate a particular patient's anatomy so as to guide an endotracheal tube. In other words, the Salerno device must have sufficient rigidity to maintain its shape as the tube is slid over the probe, similar to the malleable guides discussed in the present specification at page 3. By contrast, the claimed viewing device is flexible so as to be guided down the endotracheal tube without disturbing the

tube itself. The Salerno device, if used to inspect an already placed endotracheal tube it would be too stiff to easily follow the path of the tube while being pushed from the outside. The claims are amended to further clarify this feature.

Applicants also respectfully disagree with the statement in the Office Action that the claim terms main portion and distal portion "do not require that the main and distal portions have different properties." (Office Action at p. 7). The claims as amended state that the main portion is flexible and the distal portion is substantially rigid. The entire probe 14 of Salerno, however, is malleable. Indeed, there is no teaching in Salerno that sections of the probe can have different rigidity properties. Therefore, since the entire probe is disclosed as being malleable, the Salerno probe cannot be both substantially rigid for the distal portion as well as a flexible for the main portion.

Therefore, for these reasons the Salerno reference does not anticipate any of claims 1-3, 5, 8, 9, 11, 12, 37, 39, and 40.

2. Obviousness Rejection - Claims 4, 10, 13-17, 19-23, 25-36, 38, 41-42

Claims 4, 10, 13-17, 19-23, 25-29 are rejected as obvious in view of the Koyata reference. Claims 4, 13-17, 19-23, 25-26 and 38 are rejected as obvious in view of the Hake reference. Claims 41-42 are rejected as obvious in view of the Salerno reference.

The Patent Office bears the burden of factually supporting and establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); MPEP §2142. Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Id.* at 1532, 28 USPQ2d at 1956. When the

references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2142, *citing, In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *Id.*

Applicants submit that the Office Action fails to establish a *prima facie* case of obviousness. As such, Applicants respectfully request that the rejections on the basis of §103(a) be withdrawn.

A. Claims 4, 13-17, 19-23, 25-29 And 38 Are Not Obvious

As stated above, in order to establish a *prima facie* case of obviousness, the prior art reference must teach or suggest all the claim limitations. MPEP §2142. With regard to the Hake and Koyata references, it is conceded in the Office Action that the specific offset angle, offset distance, and radius of curvature specified in the claims are not disclosed by the prior art. The Office Action further fails to provide any evidence of a suggestion for these requirements in the prior art. As such, no *prima facie* case of obviousness is made.

Also, for the reasons discussed above, Applicants submit that neither the Koyata reference or the Hake reference disclose the combination of a substantially fixedly rigid distal portion and a flexible main portion. Therefore, no *prima facie* case of obviousness has been demonstrated.

In Applicant's first response, it was also pointed out that the Office Action failed to establish any teaching of a suggestion to modify the Koyata or Hake references to arrive at the claimed invention. The response in the Office Action is the unsupported assertion that the modifications to the prior art would have been within the level of ordinary skill at the time the claimed invention was made. (Office Action at p. 7). With all due respect, whether a modification was within the level of ordinary skill begs the question of whether one would have been motivated to make the modification absent teachings from the present application. Again, the Office Action fails to provide any evidence of a teaching or suggestion in the prior art to modify the cited art to arrive at the claimed invention. As such, the rejection based on obviousness should be withdrawn.

A stated objective of the claimed invention is to provide a device that can be guided through an endotracheal tube that may include a build-up of biological material without scraping the biological material, and thereby obscuring the endoscopic view. No similar objective is disclosed in any of the cited prior art. As such, there is no motivation to create the claimed specific offset angle, offset distance or radius of curvature. *See e.g., In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved.").

At best, the statement that the cited prior art references can be bent at any angle, radius and distance indicates only a motivation to try to arrive at the specified offset, radius or distance. A motivation to try, however, is insufficient to establish a motivation or suggestion to adapt a prior art reference to arrive at the invention as claimed. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986). As such, it cannot form the basis for a motivation or suggestion to alter the prior art in such a manner as to arrive at the claimed invention.

Accordingly, the rejection of claims 4, 13-17, 19-23, 25-29 And 38 should be withdrawn.

B. Claims 41 and 42 Are Not Obvious

With regard to the obviousness rejections of claims 41 and 42 in view of the Salerno patent, applicants respectfully disagree with the conclusion that placement of an endotracheal tube over a stylet would render obvious inserting the same stylet within an already placed intubation tube. Again, the Office Action provides no evidence of a teaching or suggestion in the art of using the device as described in the claimed method. As such, no *prima facie* case of obviousness is established.

Placing the stylet of Salerno within an endotracheal tube that is already in place in a patient's throat would also lack the advantages of the present invention. As claimed, the present invention includes a flexible main portion. As explained in the specification, the flexible tube is such that as the tube is guided down the endotracheal tube, the flexibility of the main portion permits the main portion to bend as it is extended down the tube. By contrast, the Salerno reference discloses a malleable probe for guiding the insertion of a tube. The probe of the Salerno

reference must have a greater degree of rigidity than the endotracheal tube being guided thereon. Otherwise the probe would not cause the endotracheal tube to bend along the guide. The present invention permits the viewing of an endotracheal tube that is already in place without adversely shifting the tube because of the flexibility of the main portion.

3. Conclusion

For the reasons stated above, Applicants traverse the rejections and request withdrawal of the rejections. Therefore, Applicants respectfully submit that the application is in condition for allowance and request same.

Respectfully submitted,

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